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Medical gloves for single use - Part 2: Requirements and testing for physical properties

EESTI STANDARDIMIS- JA AKREDITEERIMISKESKUS
ESTONIAN CENTRE FOR STANDARDISATION AND ACCREDITATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN 455-2:2024 sisaldab Euroopa standardi EN 455-2:2024 ingliskeelset teksti.	This Estonian standard EVS-EN 455-2:2024 consists of the English text of the European standard EN 455-2:2024.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 08.05.2024.	Date of Availability of the European standard is 08.05.2024.
Standard on kättesaadav Eesti Standardimis-ja Akrediteerimiskeskusest.	The standard is available from the Estonian Centre for Standardisation and Accreditation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

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EUROPEAN STANDARD

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English Version

Medical gloves for single use - Part 2: Requirements and testing for physical properties

Gants médicaux non réutilisables - Partie 2 : Exigences et essais pour propriétés physiques

Medizinische Handschuhe zum einmaligen Gebrauch - Teil 2: Anforderungen und Prüfung der physikalischen Eigenschaften

This European Standard was approved by CEN on 15 April 2024.

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This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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European foreword

This document (EN 455-2:2024) has been prepared by Technical Committee CEN/TC 205 “Non-active medical devices”, the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by November 2024, and conflicting national standards shall be withdrawn at the latest by November 2024.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN 455-2:2015.

Compared to the previous edition EN 455-2:2015, the following main changes have been introduced:

a) normative references have been revised;

b) subclause 4.2 has been updated with regard to recording the measured length ("median” has been removed);

c) Clause 5 has been updated;

d) Clause 6 has been updated;

e) Annex ZA has been updated for harmonization under Medical Device Regulation (EU) 2017/745 (MDR).

This document has been prepared under a standardization request addressed to CEN by the European Commission. The Standing Committee of the EFTA States subsequently approves these requests for its Member States.

For the relationship with EU Legislation, see informative Annex ZA, which is an integral part of this document.

The EN 455 series consists of the following parts under the general title “*Medical gloves for single use*”:

— *Part 1: Requirements and testing for freedom from holes;*

— *Part 2: Requirements and testing for physical properties;*

— *Part 3: Requirements and testing for biological evaluation;*

— *Part 4: Requirements and testing for shelf life determination.*

The following part is under development:

— *Part 5: Extractable chemical residues.*

A list of all parts in a series can be found on the CEN website.

Any feedback and questions on this document should be directed to the users’ national standards body. A complete listing of these bodies can be found on the CEN website.

According to the CEN-CENELEC Internal Regulations, the national standards organisations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

1 Scope

This document specifies requirements and gives test methods for physical properties of single-use medical gloves (i.e. surgical gloves and examination/procedure gloves) in order to ensure that they provide and maintain in use an adequate level of protection from cross contamination for both patient and user.

This document does not specify the size of a lot. Attention is drawn to the difficulties that can be associated with the distribution and control of very large lots. The recommended maximum individual lot size for production is 500 000.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN ISO 15223-1:2021, *Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements (ISO 15223-1:2021)*

EN ISO 20417:2021, *Medical devices — Information to be supplied by the manufacturer (ISO 20417:2021, Corrected version 2021-12)*

ISO 23529:2016, *Rubber — General procedures for preparing and conditioning test pieces for physical test methods*

ISO 188:2023, *Rubber, vulcanized or thermoplastic — Accelerated ageing and heat resistance tests*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp/

— IEC Electropedia: available at https://www.electropedia.org/

3.1
medical gloves for single use
gloves intended for use in the medical field to protect patient and user from cross-contamination

3.2
surgical gloves
sterile, anatomically shaped medical gloves with the thumb positioned towards the palmar surface of the index finger rather than lying flat, and intended for use in invasive surgery

3.3
examination gloves
procedure gloves
sterile or non-sterile medical gloves, which can be anatomically shaped, intended for conducting medical examinations, diagnostic and therapeutic procedures and for handling contaminated medical material